

filed, had possession of the claimed invention. This rejection is based on the Examiner's view that the prior amendment of claims 1-12 to require the coating of a "non-polymeric" medical device to constitute new matter. Claim 11 is further rejected under 35 U.S.C. § 112, second paragraph as indefinite on the grounds that it is not clear that the medical device substrates listed in the claim may be non-polymeric.

Claims 1-2, 4-8, 10-12 and 14-15 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent Application Ser. No. 09/836,161 (U.S. Patent Application Publication No. U.S. 2002/0051845 A1) by Mehta, *et al.* ("Mehta").

Claims 3, 7, 9 and 13 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Mehta.

The Applicant has carefully reviewed the March 17, 2003 Final Office Action. The Applicant is requesting entry of the foregoing amendments to place the claims in allowable condition.

For the reasons set forth in the following remarks, the Applicant believes that upon entry of the foregoing amendments, claims 1-15 would be in allowable form. The Applicant therefore respectfully requests reconsideration of the pending rejections and issuance of a Notice of Allowance for claims 1-15.

1. Mehta Is Not Prior Art To The Present Application.

Claims 1-2, 4-8, 10-12 and 14-15 stand rejected under 35 U.S.C. § 102 (e) as anticipated by Mehta, and claims 3, 7, 9 and 13 stand rejected under § 103(a) as unpatentable over Mehta. The application filing date of Mehta is April 17, 2001. The Applicant submits herewith a declaration demonstrating that, for the subject matter of the rejected claims, the Applicant is entitled to an invention date earlier than April 17, 2001. Because the invention date pre-dates Mehta's filing date, Mehta is not prior art to claims 1-15.

The Applicant's declaration establishes that he had conceived of the subject matter of the pending claims before April 17, 2001, and exercised the required diligence from before this date. Specifically, Exhibit A to the declaration, an internal invention disclosure document prepared in 2000, provides evidence of conception by 2000. Further, the Applicant has declared that substantially the entire focus of his employment during the relevant period was devoted to completion of the claimed invention, thereby demonstrating diligence. Alternatively, the invention disclosure establishes that there was an actual reduction to practice in a bench test in 2000, well prior to the April 17, 2001 date. Thus, the Applicant is

entitled to an invention date earlier than April 17, 2001.¹

Because Mehta cannot be used as prior art against claims 1-15, the pending § 102(e) and § 103(a) rejections must be withdrawn.

2. No New Matter Was Added By The January 3, 2003 Amendments.

The Applicant respectfully traverses the rejection of claims 1-15 under § 112, first paragraph, on the grounds that the original disclosure adequately supports the previous amendments to claims 1 and 12.

In the pending Office Action, the Examiner states that the amendments to claims 1 and 12 to require coating of a non-polymeric medical device “appears to be new matter,” as the Examiner “cannot find such a limitation in the originally-filed disclosure,” and has taken the position that “there does not appear to be [a] basis in the originally filed disclosure for claiming all non-polymers.” March 17, 2003 Office Action at 2-3.

The Applicant respectfully submits that rather than attempting to “claim[] all non-polymers,” the amendments to claims 1 and 12 are *limiting*, *i.e.*, they narrow the claims from the broad scope of the original disclosure, and that this limitation is inherent in the matter present in the original disclosure.

Inherency is established where the matter at issue “is necessarily present in the thing described ... and that it would be so recognized by persons of ordinary skill.” MPEP § 2163.07(a) (quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)). In this case, the original disclosure identifies a variety of medical devices. These devices are well recognized in the art as being typically formed of either a polymer or non-polymer material. For example, the balloon catheters identified in the original specification are typically constructed with polymer materials, while items such as stents are typically made from non-polymer materials (*e.g.*, metals). *See, e.g.*, Specification at 9:12-14 (identifying a number of medical devices compatible with the present invention). Thus, inherent in the original disclosure is the concept of coating of both polymeric and non-polymeric medical devices. Accordingly, the Applicant’s amendments to claims 1 and 12 reflect a decision to *narrow* the scope of the claims in the present case to only a portion of the matter originally disclosed, not expand the claims to encompass new matter.

¹ As permitted under MPEP § 715.07, the applicant has blocked out the month and day of the dates in the attached document, while leaving the year (2000) visible to provide the required showings prior to the April 17, 2001 reference date.

In view of the Applicant's broad original disclosure and narrowing amendments, the Applicant respectfully submits that no new matter has been added, and that the originally-filed specification adequately establishes for the purposes of § 112, first paragraph, that the Applicant was in possession of the claimed invention at the time of filing.

3. Claim 11 Is Sufficiently Definite Under § 112, Second Paragraph.

The Applicant respectfully traverses the rejection claim 11 under § 112, second paragraph on the grounds that this claim is sufficiently definite under the statute.

Claim 11 depends from claim 1, which now recites non-polymeric medical devices. Claim 11 further limits the medical devices to the group consisting of "a stent, a peripherally inserted central catheter, an angio-catheter, a stent-graft, a vena-cava filter, and an aneurysm coil." The March 17, 2003 Office Action states the grounds for rejection of this claim as indefinite as: "It is not clear to [the] Examiner that all of these substrates may be non-polymeric."

The Applicant respectfully submits that claim 11 is sufficiently definite. As noted in the preceding section, the originally-filed disclosure inherently covers both polymeric and non-polymeric medical devices. The Applicant has elected by the amendments to independent claims 1 and 12 to limit the claims to non-polymeric medical devices. As currently worded, claim 11 unambiguously defines exactly the scope of the claim, and does so in a manner readily understood by one of ordinary skill: to literally infringe this claim, a medical device: (i) must be one of the medical devices in the recited group; and (ii) must be non-polymeric. No further information is required for one of ordinary skill to understand the scope of this claim. In view of this definitive recitation of claim scope and the original disclosure, the Applicant respectfully maintains claim 11 is sufficiently definite under § 112, second paragraph, and requests the pending rejection of claim 11 be reconsidered and withdrawn.

4. Claims 16-20 Have Been Canceled, As Required.

In response to the requirement that non-elected claims 16-20 be canceled, the Applicant is requesting cancellation of these claims, without prejudice to the subject matter contained therein.

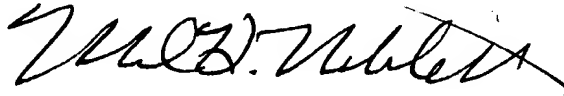
Conclusion

In view of the foregoing requested amendments and remarks, it is respectfully submitted that entry of the proposed amendments would place presently pending claims 1-15 in condition for allowance. The Applicant therefore earnestly solicits entry of the amendments and issuance of a Notice of Allowance for claims 1-15.

The Examiner is invited to contact the undersigned at (202) 220-4232 to discuss any matter concerning this application.

The Office is authorized to charge any underpayment or credit any overpayment to Kenyon & Kenyon Deposit Account No. 11-0600.

Respectfully submitted,



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